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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,097	06/27/2001	Jonathan S. Duke-Cohan	00530-089002	1296

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EXAMINER

HADDAD, MAHER M

ART UNIT PAPER NUMBER

1644

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/787,097	<b>Applicant(s)</b> DUKE-COHAN ET AL.	
	<b>Examiner</b> Maher M. Haddad	<b>Art Unit</b> 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**P riod for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 October 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) 4,5,7-19 and 28-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 20-23 is/are rejected.
- 7) ☒ Claim(s) 2,3,6 and 24-27 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All   b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)              | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5</u> . | 6) <input type="checkbox"/> Other: _____                                    |

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DETAILED ACTION

1. Claims 1-37 are pending.
2. Applicant's election without traverse of Group III, claims 1-3, 6 and 20-27, is acknowledged.
3. Claims 4, 5, 7-19 and 28-37 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to nonelected inventions.
4. Claims 1-3, 6 and 20-27 are under examination as they read on an an isolated DNA comprising SEQ ID NO:13 encoding polypeptide of SEQ ID NO:12, vectors, host cells, and methods of producing the polypeptide.
5. Claims 6 <sup>and</sup> 24-27 are objected to because it is dependent on a non-elected claim 5 and should be written as an independent claim.
6. The following is a quotation of the second paragraph of 35 U.S.C. 112.  
*The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.*
7. Claims 1 and 20-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
  - A) The recitation of "hybridizes under highly stringent conditions" in claim 1 is ambiguous. Although the specification discloses on page 21 lines 20-28 general parameters for calculating such conditions, it is unclear which conditions are actually claimed.

It is suggested that Applicant amend the claims to recite a particular set of hybridization and wash conditions, such as those exemplified on page 21 of the specification, to overcome this rejection.
8. The following is a quotation of the first paragraph of 35 U.S.C. 112:  
*The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.*

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9. Claims 1 and 20-23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the nucleotide sequence of SEQ ID NO:13 encoding an amino acid sequence of SEQ ID NO:12 for detection assay; does not reasonably provide enablement for any isolated DNA comprising: (a) any nucleic acid sequence that encodes any polypeptide that enhances spreading of a macrophage or a monocyte and that "hybridizes under highly stringent conditions" to the complement of a sequence that encodes a polypeptide with an amino acid sequence of SEQ ID NO 12 or (b) the complement of the nucleic acid sequence in claim 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification does not provide a sufficient enabling description of the claimed invention. The specification discloses only a single nucleic acid sequence (SEQ ID NO:13) encoding a single polypeptide (SEQ ID NO:12) with a disclosed ability to regulate the immune response on page 14 at lines 4-6. The instant claims encompass in their breadth *any* isolated nucleic acid which either encodes any polypeptide of SEQ ID NO: 12 or the complement of the nucleic acid sequence; or *any* nucleic acid that "hybridizes under highly stringent conditions", including those that comprise a "fragment" of SEQ ID NO: 13.

The terms "comprising" and "encodes" in claim 1 are open-ended, they expand the nucleic acid portions of SEQ ID NO: 13 to include additional non disclosed nucleic acids outside of the what hybridizes "to the complement of a sequence that encodes a polypeptide with an amino acid sequence of SEQ ID NO:12". Meinkoth *et al* in Analytical Biochemistry (138:267-284, 1984) indicate factors that affect nucleic acid hybridization such as probes length of the shortest chain in the duplex, the ionic strength, base composition and the concentration of the helix destabilizing agents (page 269, left column 2<sup>nd</sup> and 3<sup>rd</sup> paragraphs in particular). The instant claim language encompass subsequences. For example, claim 1 recites an isolated DNA comprising a nucleic acid sequence that encodes a polypeptide. Such a recitation does not require that the nucleic acid encode the full length sequence set forth in SEQ ID NO:12; but rather encompasses *any subsequences*. However, the specification does not provide sufficient guidance as to which subsequences of SEQ ID NO:13 would hybridize under highly stringent conditions to complementary DNA encoding SEQ ID NO:12. Neither the specification provides any working examples of any subsequences. Thus it would require undue experimentation of the skilled artisan to determine which subsequences of SEQ ID NO: 13 would hybridize under stringent conditions to complementary DNA encoding SEQ ID NO:12.

The fact that two nucleic acid sequences will hybridize under stringent conditions does not in and of itself require that the two sequences share any functional activity. Further, it was well known in the art at the time the invention was made that hybridization could occur between two sequence based upon short stretches of 100% identity. Thus a great deal of sequence variability *with respect to the full-length nucleic acid* is possible. In the absence of a clear recitation that the identity is over the full length of SEQ ID NO:13 the claim reads on subsequences. Thus in the absence of a *testable function* limitations regarding both the *hybridization conditions* and the

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*sequence length over which the hybridization takes place*; does not allow the skilled artisan to make and use the hybridizing nucleic acids commensurate in scope with the instant claims without undue experimentation.

Reasonable correlation must exist between the scope of the claims and scope of enablement set forth. Without sufficient guidance, the changes which can be made in the instantly recited nucleic acid sequence is unpredictable, as is the identity of which subsequences would hybridize to SEQ ID NO:1; thus the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue.

9. Claims 1 and 20-23 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is in possession of an isolated DNA of SEQ ID NO: 13 encoding amino acid of SEQ ID NO:12.

Applicant is not in possession of any isolated DNA comprising: (a) any nucleic acid sequence that encodes a polypeptide that enhances spreading of a macrophage or a monocyte and that "hybridizes under highly stringent conditions" to the complement of a sequence that encodes a polypeptide with an amino acid sequence of SEQ ID NO 12 or (b) the complement of the nucleic acid sequence in claim 1.

Applicant has disclosed only nucleic acid of SEQ ID NO: 13; therefore, the skilled artisan cannot envision all the contemplated nucleic acid sequence possibilities recited in the instant claims. Consequently, conception cannot be achieved until a representative description of the structural and functional properties of the claimed invention has occurred, regardless of the complexity or simplicity of the method. Adequate written description requires more than a mere statement that it is part of the invention. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC1993). The Guidelines for the Examination of Patent Application Under the 35 U.S.C.112, ¶ 1 "Written Description" Requirement make clear that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 20001, see especially page 1106 3<sup>rd</sup> column).

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Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed.” (See page 1117.) The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See Vas-Cath at page 1116.). Consequently, Applicant was not in possession of the instant claimed invention. See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.

Applicant is directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

*(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.*

11. Claim 1 rejected under 35 U.S.C. 102(a) as being anticipated by Nagase *et al* (GenBank accession No. AB011120, April 1998).

Nagase et al teach a 5,632 nucleic acid sequence that encodes a polypeptide that hybridizes under highly stringent conditions to the complement of a sequence that encodes a polypeptide with an amino acid sequence of SEQ ID NO:12 at positions (aa 978-1429). The term “comprising” and “encodes” are open-ended, they would open up the claim to include the reference 5,632 nucleic acid sequence. The recitation “enhances spreading of a macrophage” is considered inherent property of the reference nucleic acid because the reference DNA is the same as the claimed DNA.

The reference teachings anticipate the claimed invention.

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

*(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.*

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13. Claims 20-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nagase *et al* (GenBank accession No. AB011120, April 1998) in view of Darnell *et al*.

The teachings of Nagase *et al* reference have been discussed, *supra*.

The claimed invention differs from the reference teachings only by the recitation of a host cell a vector in claim 20, wherein the nucleic acid sequence is operably linked to a regulator element which allows expression of said nucleic acid in a cell in claim 21, a cultured cell comprising the vector in claim 22 and a method for producing a polypeptide in claim 23.

Darnell *et al* teach that in order to prepare an unlimited amount of a pure gene, a vector containing the gene can be grown in a host cell and DNA extracted. Darnell *et al* also teach an expression vector with promoter in order to take advantage of "bacterial tricks" that increase mRNA synthesis to produce large quantities of desired proteins using a eukaryotic vector and host cell, or a prokaryotic and bacterial vector and host cell (page 255-258 in particular).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to express the DNA taught by the Nagase *et al* using the vectors, host cells and the method of producing the polypeptide as taught by Darnell *et al*.

One of ordinary skill in the art at the time the invention was made would have been motivated to do so because a vector containing the a gene that grown in a host cell offers to prepare an unlimited amount of a pure gene as well as to produce large quantities of desired proteins as taught by Darnell *et al*.

From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

14. Claims 2-3 are objected to as being dependent upon a rejected base claim 1, but would be allowable if rewritten in independent form including all of the limitations of the base claim.

15. Claims 6 and 24-27 objected to as being dependent upon a non-elected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

16. No claim is allowed.

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17. Formal drawings have been submitted which fail to comply with 37 CFR 1.84. Please see the enclosed form PTO-948.

**18. 1. Correction of Informalities -- 37 CFR 1.85**

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the "Notice of Allowability." Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136 for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

**2. Corrections other than Informalities Noted by Draftsperson on form PTO-948.**

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.


**Timing of Corrections**

Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.85(a). Failure to take corrective action within the set period will result in **ABANDONMENT** of the application.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad, whose telephone number is (703) 306-3472. The examiner can normally be reached Monday to Friday from 8:00 to 4:30. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached at (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Maher Haddad, Ph.D.  
Patent Examiner  
Technology Center 1600  
December 30, 2002

  
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